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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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ART UNIT	**PAPER NUMBER**
1646	9

DATE MAILED: 09/23/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire _____ month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-42 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☐ Claim(s) _____ is/are rejected.
☐ Claim(s) _____ is/are objected to.
☒ Claim(s) ~~1-40~~ 1-42 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

★ U.S. GPO: 1996-404-496/40517

Part III: Detailed Office Action

Restriction Requirement:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-19, drawn to anti-thrombopoietin receptor antibodies, classified in class 530, subclass 387.9.

II. Claims 20-28, drawn to a phage display library, classified in class 435, subclass 69.7.

III. Claims 29-32, drawn to a method of treatment using anti-TPO-receptor antibodies, classified in class 424, subclass 143.1.

IV. Claims 33-36, drawn to nucleic acids, vectors, host cells and recombinant production of anti-thrombopoietin receptor antibodies , classified in class 435, subclass 69.1.

V. Claim 37, drawn to an agonist antibody that binds a MuSK receptor, classified in class 530, subclass 387.9.

VI. Claims 38-40 and 42, drawn to a method of activating a receptor using a single chain antibody, classified in class 424, subclass 135.1.

VII. Claim 41, drawn to a method of treatment using an anti-musk receptor antibody, classified in class 424, subclass 143.1.

The inventions are distinct, each from the other because:

Inventions I-IV pertain to the production and use of anti-thrombopoietin receptor antibodies, all of which inventions are separate and distinct from inventions V and VII, which are drawn to the production and use of anti-MuSK receptor antibodies. As the thrombopoietin receptor and MuSK receptor have distinct structures and functions, and as antibodies to those receptors would likewise be expected to have distinct structures and functions, the two groups of inventions are separate and distinct.

The products of Invention I are distinct from the products of Invention II because they are physically and functionally distinct. Invention I encompasses numerous types of antibodies, including single chain antibodies, as displayed in the phage display library of Invention II. However, the

production of the antibodies of Invention I does not require the phage display library of Invention II, and the phage display library of Invention II requires critical elements not required for invention I, and which require a separate and divergent search. Therefore, restriction between these two inventions is proper.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product may be used in *in vitro* assays, or for the purification of thrombopoietin receptors.

The nucleic acids of Invention IV are related to the antibody of Invention I by virtue of encoding same. The DNA molecule has utility for the recombinant production of the antibody in a host cell, as recited in claim 36. Although the DNA molecule and antibody are related since the DNA encodes the specifically claimed antibody, they are distinct inventions because they are physically and functionally distinct chemical entities, and the antibody product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the antibody, such as nucleic acid hybridization assay.

Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the single chain antibodies may be used for *in vitro* assays or purification of thrombopoietin (TPO) receptor.

Inventions II and III are separate and distinct, wherein the products of Invention II may be neither made by nor used in the methods of Invention III.

Inventions II and IV are distinct because although both involve recombinant production of antibodies, the outcome of that recombinant production is distinct, invention II providing a diverse

library of antibodies and the method of Invention IV providing a single type of antibody at one time, and further because the two groups of methods use patentably distinct vector and expression systems.

The methods of Invention VI are separate and distinct from the methods of inventions III and IV wherein the various methods utilize different reagents and method steps for the accomplishment of distinct purposes.

The products of invention II are separate and distinct from the methods of invention VI wherein the products (a phage display library) may be neither made by nor used in the methods.

The methods of Invention III are separate and distinct from the methods of invention III wherein the various methods utilize different reagents and method steps for the accomplishment of distinct purposes. The products of Invention IV are distinct from the method of Invention III wherein the products may be neither made by nor used in the methods.

Inventions V and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of invention V may be used for the purification of MuSK receptors, or in *in vitro* immunoassays.

The method of Invention VI is separate and distinct from the antibody of invention V wherein the antibody may not be made by the method, nor is it required for the method.

The methods of Inventions VI and VII are separate and distinct because although there may be species of antibody which could be used in both methods, the groups of antibodies used in the methods are largely non-overlapping (single chain vs. anti-MuSK), and because the two inventions require divergent and largely non-overlapping searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Election of species requirement:

In the event that election is made of Invention I, a further election of species is required as follows:

This application contains claims directed to the following patentably distinct species of the claimed invention: 12E10, 12B5, 10F6, 12D5, Ab1, Ab2, Ab3, Ab4, Ab5 and Ab6. These species are considered to be distinct because each has a separate and distinct physical structure that requires separate search.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 12, and 16-19 are generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 8:00 A.M. to 4:30 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Paula Hutzell, Ph.D, can be reached at (703)308-4310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 305-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. **Please** advise the Examiner at the telephone number above when an informal fax is being transmitted.

Lorraine Spector, Ph.D.
Primary Examiner

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